

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

**IN RE: ETHICON, INC. PELVIC  
REPAIR SYSTEM PRODUCTS  
LIABILITY LITIGATION**

**Master File No. 2:12-MD-02327  
MDL No. 2327**

**JOSEPH R. GOODWIN  
U.S. DISTRICT JUDGE**

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION  
TO EXCLUDE THE GENERAL OPINIONS  
OF DEFENSE EXPERT CHARLES HANES, M.D.**

The proffered general causation/liability opinions of Charles Hanes, an expert for the Defendants, fail to pass the *Daubert* standard. Dr. Hanes is not qualified to discuss design issues regarding Defendants' transvaginal mesh devices because he has extremely limited knowledge of the design process. Dr. Hanes also lacks the expertise to opine about whether the warnings for those products were sufficient. As to methodology, Dr. Hanes's opinions are unreliable because; 1) he did not review any of the key documents or depositions that would have explained Defendants' design procedures or the safety of the devices<sup>1</sup>, 2) he did not review any literature on discussing the design issues for the devices he opines on, 3) he is unaware of materials that contradict his opinions on the key liability and design issues for the devices he opines on, and 4) he admitted he has never draft any warnings statements for medical devices.. For all of these reasons, Dr. Hanes should be excluded from giving the opinions that form the foundation of his analysis.

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<sup>1</sup> In fact, Dr. Hanes admitted he did not review a single company document or company deposition.

As Dr. Hanes demonstrated during his deposition, he does not have the qualifications to give opinions about product design or about warnings, and he did not use a reliable methodology in reaching his opinions.

### LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, “the district court must decide whether the expert has ‘sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.’” *Belk, Inc. v. Meyer Corp.*, U.S., 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents “scientific knowledge,” meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert’s opinions “fit” the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

To meet the standard of reliability, the testimony “must be supported by appropriate validation—i.e., ‘good grounds,’ based on what is known. In short, the requirement that an

expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995).

There are five factors courts often consider, taken from the *Daubert* opinion, in assessing the reliability of expert testimony:

- (1) whether the testimony has been tested,
- (2) whether it has been published or exposed to peer review,
- (3) its rate of error,
- (4) whether there are standards and controls over its implementation, and
- (5) whether it is generally accepted.

*See Cavallo v. Star Enterprise*, 100 F.3d 1150, 1158 (4th Cir. 1996). However, "the factors discussed in *Daubert* were neither definitive, nor exhaustive." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

Courts should focus on expert witnesses' "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because "*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder." *Cavallo*, 100 F.3d at 1158.

### **ARGUMENT**

There are several reasons that this Court should prohibit Dr. Hanes from giving opinions about the design of the transvaginal mesh devices or about product warnings for the devices he opines on. Dr. Hanes's report touches on several topics, but his reports have two general opinions:

- “In short, I believe that Prolift and Prolift +M were safe and effective, state of the art products for the repair of pelvic organ prolapse. They were not defectively designed.”<sup>2</sup>
- “In short, I believe that TVT, TVT-O, TVT Abbrevio and TVT Exact were safe and effective, state of the art products for the repair of stress urinary incontinence. They were not defectively designed.”<sup>3</sup>
- “The instructions for use provided with Prolift and Prolift +M were adequate and appropriately warned surgeons of any risks that were unique to those products.”<sup>4</sup>
- “The instructions for use provided with TVT, TVT-O, TVT Abbrevio and TVT Exact were adequate and appropriately warned surgeons of any risks that were unique to those products.”<sup>5</sup>

This Court should preclude Dr. Hanes from opining about design issues and about warnings, for the reasons stated below.

**I. Dr. Hanes should be precluded from giving design opinions because he did not review any Coloplast documents related to product design and safety of the devices, he did not review any deposition testimony related to product design and safety of the devices, he has no knowledge about the design process, he did not review literature on key design features of the devices, he is unaware of any materials that contradicts his design opinions, and he relies on personal complication rates that he admits he doesn’t know and cannot be objectively verified.**

Dr. Hanes ignored all internal documents, all depositions and he demonstrated a complete lack of knowledge regarding the product design process.<sup>6</sup> This Court has previously recognized

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<sup>2</sup> **Exhibit B:** Hanes Prolift/Prolift + M Expert Report, page 4

<sup>3</sup> **Exhibit C:** Hanes TVT R, TVT O, TVT A, TVT E Report, page 4

<sup>4</sup> **Exhibit B:** Hanes Prolift/Prolift + M Expert Report, page 23

<sup>5</sup> **Exhibit C:** Hanes TVT R, TVT O, TVT A, TVT E Report, page 30

<sup>6</sup> **Exhibit D:** Hanes Deposition, July 12, 2019, pages 56:57:4; 57:11-57:23

the importance of reviewing internal documents before giving opinions on design issues.

*Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at \*14 (S.D. W. Va. Apr. 24, 2015) (excluding expert's design opinions on design protocols because he had failed to review internal documents). In his deposition, Dr. Hanes stated that he did not review any internal documents or depositions in formulating his opinions.

**Q: Have you reviewed every item on the materials list?**

A: No.

**Q: Did you review any Ethicon corporate documents in forming your general causation opinions?**

A: I did not specifically review any Ethicon documents.

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**Q: Okay. Did you review any deposition testimony?**

A: In preparing these documents, no, I did not.<sup>7</sup>

Because he did not review any relevant design documents or relevant deposition testimony on the design and safety of the devices he opines on Dr. Hanes lacks the required knowledge to give a reliable opinion about the design of these devices. Dr. Hanes's failure to review such important documents and deposition testimony leaves him without a reasonable foundation for an opinion about the devices' product design. Dr. Hanes should have reviewed company documents and depositions in forming his opinions about the design of the devices he opines on.

Dr. Hanes's lack of knowledge on these points demonstrates that he does not have the expertise necessary to opine about issues of product design, and his failure to review design documents and company depositions in formulating his opinions was not a reliable methodology.

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<sup>7</sup> **Exhibit D:** Hanes Deposition, July 12, 2019, pages 56:57:4; 57:11-57:23

Moreover, Dr. Hanes's testimony reveals he ignored important medical literature on the devices he opines on. Dr. Hanes will likely try to excuse away ignoring all documents and deposition testimony by solely relying on his clinical experience and literature. But a review of his testimony reveals he failed to do a balanced literature review and ignored articles that do not support his opinions.

18 **Q: Okay. So, just so that I have an**  
19 **understanding, as far as medical literature, have**  
20 **you seen any medical literature indicating that**  
21 **Ethicon's mesh can degrade after a proper**  
22 **implantation?**

23 A: No, I have not.

24 **Q: Have you seen any medical literature**  
1 **indicating that a properly placed Ethicon mesh**  
2 **product can rope or curl after implantation?**

3 A: I can't say that I've seen any  
4 literature that has said that.

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14 **Q: Okay. Have you reviewed any medical**  
15 **literature indicating that a properly placed**  
16 **Ethicon mesh product can migrate after**  
17 **implantation?**

18 A: No.

19 **Q: Have you seen any medical literature**  
20 **indicating that a properly placed Ethicon mesh**  
21 **product can bunch up after implantation?**

22 A: No.

23 **Q: And only two more. Have you seen any**  
24 **medical literature indicating that a properly**  
1 **placed Ethicon mesh product can harden or stiffen**  
2 **after implantation?**

3 A: No.

4 **Q: Have you seen any medical literature**  
5 **indicating that a properly placed Ethicon mesh**  
6 **product can fray after implantation?**

7 A: No.

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21 **Q: Have you reviewed any medical articles**

22 **that have discussed the edges of the TVT and**  
23 **Prolift mesh being abrasive and sharp?**

24 A: I have not seen any medical literature  
1 that says that.<sup>8</sup>

Dr. Hanes admits he is unaware of the key safety and design issues with Defendants' mesh devices raised in this litigation, raised in peer-reviewed journal articles, raised in depositions, raised in company documents and raised at the prior trials conducted before this Court.

9 **Q: Okay. And do you have an understanding**  
10 **as to the flexibility or stiffness of the Ethicon**  
11 **mesh?**

12 MR. BARTON:

13 Object to the form.

14 A: I don't -- I don't know any of the --  
15 enough about that to really be able to comment.<sup>9</sup>

Finally, while Dr. Hanes purports to rely on his clinical experience, specifically low complication and high satisfaction rates from his own practice, for the primary basis for his opinions, he admits he has no idea what his complication rate is. Thus, these supposed complication and satisfaction rates exist only in Dr. Hanes's mind and certainly can not be objectively verified.

20 **Q: Okay. Do you keep a patient registry**  
21 **for the patients in whom you have implanted**  
22 **transvaginal mesh products?**

23 A: No.

24 **Q: So is it fair to say that you can't say**  
1 **with accuracy what your complication rates are**  
2 **with respect to the transvaginal mesh products**  
3 **that you have implanted?**

4 MR. BARTON:

5 Object to the form.

6 A: Yeah. I -- I would not be able to  
7 hazard a guess on what my complication rate is.

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<sup>8</sup> **Exhibit D:** Hanes Deposition, July 12, 2019, pages 58:18-59:4;59:14-60:8; 61:212-62:1

<sup>9</sup> **Exhibit D:** Hanes Deposition, July 12, 2019, pages 84:9-15

8 I think it's -- it's a -- you know, it would be  
 9 considered a very acceptable rate, but I -- I  
 10 don't know specifically what it would be.<sup>10</sup>

Dr. Hanes is relying on complication rates from his own practice, and yet he has no foundation whatsoever or idea what the complication rates are. Plaintiffs have no reasonable way of testing the veracity of Dr. Hanes's claims of low complications and high satisfaction rates, which exist only in his mind. Because there is no foundation for this testimony, Dr. Hanes should, at the very least, be prohibited from testifying about complication rates or satisfaction rates from his own practice. In addition, this testimony further demonstrates that there is no solid foundation for his general opinions about the safety of the design he opines on.

**II. Dr. Hanes has no expertise in the area of warnings and instructions, so those opinions should also be excluded.**

The final major reason that Dr. Hanes should be excluded from giving design opinions is that he has no expertise in the area of product warnings. Product warnings are one part of the design of a medical device. Dr. Hanes admitted he has never “drafted a warning for a medical device of pharmaceutical company’s product” and the only claimed source of supposed expertise is “in the course of training doctors...”<sup>11</sup>

This Court has previously recognized the importance of an expert’s lack of experience in drafting product warnings or being involved in the process. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), *amended on reconsideration in part* (June 14, 2013) *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 704 n.2 (S.D.W. Va. 2014) (allowing Dr. Rosenzweig’s testimony on warnings, stating that “Dr. Shull *admitted* that he had not developed product warnings, had no experience in that area, and did not hold himself out as an expert in product

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<sup>10</sup> **Exhibit D:** Hanes Deposition, July 12, 2019, pages 70:20-71:10

<sup>11</sup> **Exhibit D:** Hanes Deposition, July 12, 2019, pages 86:5-14

warnings. ... Dr. Rosenzweig has made no similar admissions.”). That same analysis applies here to Dr. Hanes, who has admitted that he is no experience or expertise with product labels and warnings – and only claimed experience was training doctors.

### CONCLUSION

For all of these reasons, this Court should preclude Dr. Hanes from giving any opinions about the Prolift/Prolift +M/TVT R/TVT O/TVT A/TVT E transvaginal mesh product design, including but not limited to the opinions that the devices are not defectively designed, the benefits outweigh the risks, the devices are state of the art and the devices are reasonably safe and effective. Dr. Hanes’s testimony indicates that he is not qualified to discuss design issues, because she does not have the necessary “knowledge, skill, experience, training, or education” about the design process. *See* Fed. R. Evid. 702. Dr. Hanes did not review any design documents or any depositions and demonstrated a lack of knowledge about that process generally. Therefore, Dr. Hanes does not possess “sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.” *See Belk*, 679 F.3d at 162.

In addition, Dr. Hanes’s failure to review any design documents and any deposition testimony so as to learn about the design of the product, including the potential hazards, as well demonstrating a lack of basic knowledge of the product basic design features, his lack of knowledge of the relevant literature, and his reliance on complication rates that exist only in his own mind, demonstrate that Dr. Hanes did not use a reliable methodology in forming his opinions. In other words, he does not have “good grounds” for his opinions on product design. *See Benedi*, 66 F.3d at 1383.

The Court should also exclude Dr. Hanes’s warnings opinions. He admits that he has no experience in drafting or contributing to product labels and warnings.

Dated: August 15, 2019

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**CERTIFICATE OF SERVICE**

I hereby certify that I filed the foregoing document on August 15, 2019, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/ Jeffrey M. Kuntz

**Attorney for Plaintiffs**